UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge **JURY TRIAL DEMANDED**

FIRST AMENDED ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., HUAHAI U.S., INC., PRINSTON PHARMACEUTICAL INC., AND SOLCO HEALTHCARE U.S., LLC AND JURY DEMAND

Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Huahai U.S., Inc. ("Huahai US"), Prinston Pharmaceutical Inc. ("Prinston"), and Solco Healthcare U.S., LLC ("Solco") (collectively, the "ZHP Defendants") answer the Third Amended Consolidated Economic Loss Class Action Complaint ("Complaint"), as follows:

The ZHP Defendants are submitting this Answer in conjunction with the upcoming TPP class trial. The ZHP Defendants reserve their right to submit a separate answer as to the consumer economic loss class claims at the appropriate time. Except as otherwise expressly set forth below, the ZHP Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of each and every allegation contained in the Complaint to the extent that such allegations

refer or relate to persons or entities other than any of the ZHP Defendants individually or the ZHP Defendants together. To the extent the ZHP Defendants admit or deny any allegations directed generally at defendants, they do so only to the extent the allegations are directed at them. Nothing in this Answer should be construed as a response to any allegations as they pertain to other defendants. Any allegation, averment, contention or statement in the Complaint not specifically and unequivocally admitted is denied.

1. The ZHP Defendants admit that Plaintiffs have brought the above-captioned lawsuit.

RESPONSE TO "INTRODUCTION"

2. The ZHP Defendants deny the allegations in Paragraph 2 of the Complaint.

3. The ZHP Defendants admit the allegations in Paragraph 3 of the Complaint except to the extent they purport to summarize public statements, the contents of which speak for themselves.

4. The ZHP Defendants deny the allegations in Paragraph 4 of the Complaint.

5. The ZHP Defendants deny the allegations in Paragraph 5 of the Complaint.

6. The ZHP Defendants deny the allegations in Paragraph 6 of the Complaint.

7. The ZHP Defendants deny the allegations in Paragraph 7 of the Complaint.

8. The ZHP Defendants deny the allegations in Paragraph 8 of the Complaint.

9. The ZHP Defendants deny the allegations in Paragraph 9 of the Complaint.

10. The ZHP Defendants deny the allegations in Paragraph 10 of the Complaint.

11. The ZHP Defendants deny the allegations in Paragraph 11 of the Complaint.

12. The ZHP Defendants deny the allegations in Paragraph 12 of the Complaint.

13. The ZHP Defendants deny the allegations in Paragraph 13 of the Complaint.

RESPONSE TO "PARTIES"

Response to "A. Consumer Class Representatives"

14. Paragraphs 14-59 of the Complaint involve the consumer class claims, which will be addressed in a separate Answer at the appropriate time.

Response to "B. The Third-Party Payor ("TPP") Class Representatives"

60. Paragraph 60 of the Complaint references a limited liability company agreement, the contents of which speak for themselves. The ZHP defendants otherwise admit the allegations in Paragraph 60 of the Complaint.

61. Paragraph 61 of the Complaint references a limited liability company agreement, the contents of which speak for themselves.

62. Paragraph 62 of the Complaint references unidentified assignment agreements, the contents of which speak for themselves.

63. Paragraph 63 of the Complaint references assignment agreements, the contents of which speak for themselves.

64. Paragraph 64 of the Complaint references an assignment agreement, the contents of which speak for themselves.

65. Paragraph 65 of the Complaint references an assignment agreement, the contents of which speak for themselves.

66. Paragraph 66 of the Complaint references a letter, the contents of which speak for themselves.

67. Paragraph 67 of the Complaint references an assignment agreement, the contents of which speak for themselves.

68. The ZHP Defendants deny the allegations in Paragraph 68 of the Complaint.

69. The ZHP Defendants deny the allegations in Paragraph 69 of the Complaint.

70. Because MADA is not serving as a representative for the TPP trial, this paragraph does not require a response.

71. Because MADA is not serving as a representative for the TPP trial, this paragraph does not require a response.

72. Because MADA is not serving as a representative for the TPP trial, this paragraph does not require a response.

73. Because MADA is not serving as a representative for the TPP trial, this paragraph does not require a response.

Response to "C. The Active Pharmaceutical Ingredient Manufacturer Defendants"

74. Paragraph 74 of the Complaint merely purports to organize the defendants. The ZHP Defendants deny that any of them manufactured valsartan API during the class period except ZHP.

Response to "1. Zhejiang Huahai Pharmaceutical Co., Ltd. Entities"

75. The ZHP Defendants deny the allegations in Paragraph 75 of the Complaint, except they admit that ZHP is a Chinese corporation, with its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China.

76. Huahai US admits that it is a wholly-owned subsidiary of ZHP, is a New Jersey corporation with its principal place of business located at 2002 Eastpark

Blvd., Cranbury, New Jersey, 08512. The ZHP Defendants also admit that Paragraph 76 of the Complaint purports to quote from a website, the contents of which speak for themselves. The ZHP Defendants otherwise Paragraph 76 of the Complaint.

77. Prinston admits that it is a wholly-owned subsidiary of PrinJohnson Biopharm, Inc. ("PrinJohnson"), of which ZHP owns approximately 93.5% through direct and indirect holdings, and that it is a Delaware corporation with its principal place of business located at 700 Atrium Drive, Somerset, NJ 08873. Prinston otherwise denies the allegations in Paragraph 77 of the Complaint.

78. Solco admits that it is a wholly-owned subsidiary of Prinston, of which ZHP owns approximately 93.5% through its direct and indirect holdings of PrinJohnson, and that it is a Delaware corporation with its principal place of business located at 700 Atrium Drive, Somerset, NJ 08873. Solco otherwise denies the allegations in Paragraph 78 of the Complaint.

79. The ZHP Defendants deny the allegations in Paragraph 79 of the Complaint, except that Paragraph 79 references an FDA document, the contents of which speak for themselves.

80. The ZHP Defendants admit the allegations in Paragraph 80 of the Complaint

81. Paragraph 81 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

Response to "2. Hetero Labs, Ltd. Entities"

82. Paragraphs 82-87 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "3. Mylan Laboratories, Ltd. Entities"

88. Paragraphs 88-93 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "4. Aurobindo Pharma, Ltd. Entities"

94. Paragraphs 94-98 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "D. The Finished-Dose Defendants"

Response to "1. The Teva Defendants"

99. Paragraphs 99-102 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "2. The Torrent Defendant"

103. Paragraphs 103-105 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "E. Retail Pharmacy Defendants"

106. Paragraphs 106-108 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "1. Walgreens"

109. Paragraphs 109-114 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "2. CVS"

115. Paragraphs 115-123 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "3. Walmart"

124. Paragraphs 124-127 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "4. Rite-Aid"

128. Paragraphs 128-130 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "5. Express Scripts"

131. Paragraphs 131-133 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "6. Kroger"

134. Paragraphs 134-136 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "7. OptumRx"

137. Paragraphs 137-138 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "8. Albertson's LLC"

139. Paragraphs 139-140 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "9. John Doe Pharmacies"

141. Paragraph 141 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

Response to "F. Wholesaler Defendants"

142. Paragraphs 142-147 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "1. Cardinal Health, Inc."

148. Paragraphs 148-150 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "2. McKesson Corporation"

151. Paragraphs 151-153 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "3. AmerisourceBergen Corporation"

154. Paragraphs 154-156 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "4. John Doe Wholesalers"

157. Paragraph 157 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

Response to "G. Repackager and Relabeler Defendants"

158. Paragraphs 158-162 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "H. True Names/John Doe Defendants 1-50"

163. Paragraphs 163-164 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

RESPONSE TO "III. JURISDICTION AND VENUE"

165. The ZHP Defendants admit that there is subject matter jurisdiction in this Court over this matter under the Class Action Fairness Act.

166. ZHP denies the allegations in Paragraph 166 of the Complaint. Solco, Prinston and Huahai US admit that this Court has personal jurisdiction over them.

167. The ZHP Defendants deny the allegations in Paragraph 167 of the Complaint.

RESPONSE TO "IV. FACTUAL ALLEGATIONS"

Response to "A. Prescription Drug Reimbursement"

168. In response to the allegations in Paragraph 168 of the Complaint, the ZHP Defendants admit that pharmaceutical manufacturers, wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs") play a role in the pharmaceutical supply chain in the United States. Otherwise, the allegations are denied.

169. In response to the allegations in Paragraph 169 of the Complaint, the ZHP Defendants admit that some pharmaceutical manufacturers produce medications that are distributed to wholesale distributors and sold to retailers.

170. In response to the allegations in Paragraph 170 of the Complaint, the ZHP Defendants admit as a general matter that certain TPPs contract with PBMs to administer their drug programs. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 170 of the Complaint.

171. The ZHP Defendants deny the allegations in Paragraph 171 of the Complaint.

172. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 172 of the Complaint as stated and therefore deny same.

173. Paragraph 173 of the Complaint includes a graphic from the Wall Street Journal, the contents of which speak for themselves. In all other respects, the allegations are denied.

174. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 174 of the Complaint as stated and therefore deny same.

Response to "B. Prescription Drug Identification and Tracing"

175. In response to the allegations in Paragraph 175 of the Complaint, the ZHP Defendants admit that the FDA assigns a National Drug Code ("NDC") to prescription medications offered for sale. The remainder of the allegations in this paragraph purport to summarize FDA documents, the contents of which speak for themselves.

176. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 176 of the Complaint, except that prescription medications offered for sale are assigned NDCs.

177. In response to Paragraph 177 of the Complaint, the ZHP Defendants admit that, as a general matter, retail prescription medication labels display the NDC of the dispensed product. In all other respects, the ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 177 of the Complaint.

178. In response to Paragraph 178 of the Complaint, the ZHP Defendants admit that, as a general matter, retail prescription medications are associated with lot numbers. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 178 of the Complaint as stated and therefore deny same.

Response to "C. The Drug Supply Chain Security Act Requires Tracing of Product"

179. Paragraph 179 of the Complaint purports to describe the requirements of the Drug Supply Chain Security Act ("DSCSA"), the contents of which speak for themselves.

180. Paragraph 180 of the Complaint purports to describe a Department of Health and Human Services report, the contents of which speak for themselves.

181. In response to the allegations in Paragraph 181 of the Complaint, the ZHP Defendants admit that the DSCSA was signed into law in 2013 and state that they are without knowledge or information sufficient to form a belief as to the truth of the of the allegations in Paragraph 181 of the Complaint that relate to other Defendants. The ZHP Defendants deny the remainder of the allegations in Paragraph 181 of the Complaint.

182. Paragraph 182 of the Complaint purports to describe the requirements of the DSCSA, the contents of which speak for themselves.

183. Paragraph 183 of the Complaint purports to describe the requirements of the DSCSA, the contents of which speak for themselves.

184. The ZHP Defendants deny the allegations in Paragraph 184 of the Complaint.

185. Paragraph 185 of the Complaint contains allegations regarding pharmacy reimbursements that are not directed to the ZHP Defendants and therefore do not require a response.

186. Paragraph 186 of the Complaint contains allegations regarding pharmacy reimbursements that are not directed to the ZHP Defendants and therefore do not require a response.

187. Paragraph 187 of the Complaint purports to summarize multiple documents, the contents of which speak for themselves.

188. Paragraph 188 of the Complaint purports to summarize a regulatory document, the contents of which speak for themselves.

189. Paragraph 189 of the Complaint purports to quote from the Walgreens Pharmacy Manual, the contents of which speak for themselves.

190. Paragraph 190 of the Complaint purports to quote from a CVS/Caremark document, the contents of which speak for themselves.

191. Paragraph 191 of the Complaint purports to describe the requirements of the DSCSA, the contents of which speak for themselves.

192. Paragraph 192 of the Complaint purports to describe the requirements of the DSCSA, the contents of which speak for themselves.

193. Paragraph 193 of the Complaint purports to describe the requirements of the DSCSA, the contents of which speak for themselves.

194. Paragraph 194 of the Complaint purports to quote from an AmerisourceBergen guide, the contents of which speak for themselves.

Response to "D. Manufacturer Defendants' VCDs Are Identifiable by NDC Information"

195. The ZHP Defendants admit that prescription drugs are sold with unique NDCs but are without knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 195 of the Complaint as stated and therefore deny same.

196. The ZHP Defendants deny the allegations in Paragraph 196 of the Complaint but admit that the recalled medications in the valsartan recall were identified by NDC.

197. Paragraph 197 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

198. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 198 of the Complaint, and therefore deny same.

199. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 199 of the Complaint, and therefore deny same.

200. Paragraph 200 of the Complaint purports to summarize an FDA press release, the contents of which speak for themselves.

201. Paragraph 201 of the Complaint purports to reference and excerpt a letter, the contents of which speak for themselves.

202. Paragraph 202 of the Complaint purports to reference and excerpt a letter, the contents of which speak for themselves.

203. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 203 of the Complaint and therefore deny same.

Response to "E. Generic Drugs Must be Chemically the Same as Branded Drug Equivalents"

204. Paragraph 204 of the Complaint purports to quote from an FDA document, the contents of which speak for themselves.

205. Paragraph 205 of the Complaint and its subparts purport to summarize an FDA document, the contents of which speak for themselves.

206. The ZHP Defendants deny the allegations in Paragraph 206 of the Complaint.

207. Paragraph 207 of the Complaint purports to summarize an FDA document, the contents of which speak for themselves.

208. Paragraph 208 of the Complaint purports to summarize an FDA document, the contents of which speak for themselves.

Response to "F. Adulterated or Misbranded Drugs"

209. Paragraph 209 of the Complaint purports to summarize a legal statute, the contents of which speak for themselves.

210. Paragraph 210 of the Complaint purports to summarize a legal statute, the contents of which speak for themselves.

211. Paragraph 211 of the Complaint purports to summarize a legal statute, the contents of which speak for themselves.

212. Paragraph 212 of the Complaint and its subparts quote from statutory provisions, the contents of which speak for themselves.

213. Paragraph 213 of the Complaint and its subparts quote from statutory provisions, the contents of which speak for themselves.

214. The ZHP Defendants deny the allegations in Paragraph 214 of the Complaint.

Response to "G. The Drugs Ingested by Plaintiffs were not Valsartan, But New, Unapproved VCDs Not of the Same Quality"

215. Paragraph 215 of the Complaint purports to quote from an FDA website, the contents of which speak for themselves.

216. Paragraph 216 of the Complaint purports to quote from FDA regulations, the contents of which speak for themselves.

217. The ZHP Defendants deny the allegations in Paragraph 217 of the Complaint.

218. The ZHP Defendants deny the allegations in Paragraph 218 of the Complaint.

219. Paragraph 219 of the Complaint purports to summarize FDA regulations, the contents of which speak for themselves.

220. The ZHP Defendants deny the allegations in Paragraph 220 of the Complaint.

221. The ZHP Defendants deny the allegations in Paragraph 221 of the Complaint.

222. The ZHP Defendants deny the allegations in Paragraph 222 of the Complaint.

223. The ZHP Defendants deny the allegations in Paragraph 223 of the Complaint.

224. The ZHP Defendants deny Plaintiffs' characterization of their allegations in Paragraph 224 of the Complaint.

Response to "H. Defendants Made False Statements in the Labeling of Their VCDs"

225. Paragraph 225 of the Complaint purports to summarize and quote from a federal regulation, the contents of which speak for themselves.

226. Paragraph 226 of the Complaint purports to summarize and quote from a federal regulation, the contents of which speak for themselves.

227. Paragraph 227 of the Complaint purports to summarize and quote from a court ruling, the contents of which speak for themselves.

228. Paragraph 228 of the Complaint purports to summarize and quote from federal regulations, the contents of which speak for themselves.

229. The ZHP Defendants deny the allegations in Paragraph 229 of the Complaint.

230. The ZHP Defendants deny the allegations in Paragraph 230 of the Complaint.

231. The ZHP Defendants deny the allegations in Paragraph 231 of the Complaint.

Response to "I. The Generic Drug Supply Chain in the United States"

232. The ZHP Defendants admit the allegations in Paragraph 232 of the Complaint as a general statement.

233. In response to Paragraph 233 of the Complaint, the ZHP Defendants admit that generic drug manufacturers may sell products to other manufacturers or

re-packagers of medication. Otherwise, they are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 233 of the Complaint, and therefore deny same.

234. In response to Paragraph 234 of the Complaint, the ZHP Defendants admit that generic drug manufacturers may contract directly with wholesalers and retail pharmacies for the sale of pharmaceutical products but deny the remainder of the allegations in Paragraph 234 of the Complaint as stated and therefore deny same.

235. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 235 of the Complaint and therefore deny same.

236. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 236 of the Complaint and therefore deny same.

Response to "J. Background on Current Good Manufacturing Practices ("cGMP")"

237. The ZHP Defendants deny the allegations in Paragraph 237 of the Complaint.

238. Paragraph 238 of the Complaint purports to quote from federal regulations, the contents of which speak for themselves.

239. Paragraph 239 of the Complaint purports to quote from federal regulations, the contents of which speak for themselves.

240. Paragraph 240 of the Complaint purports to quote from federal statutory provisions, the contents of which speak for themselves.

241. The ZHP Defendants deny the allegations of Paragraph 241 of the Complaint, except to the extent they purport to quote from a federal statutory provision, the contents of which speak for themselves.

242. Paragraph 242 of the Complaint purports to quote from federal regulations, the contents of which speak for themselves.

243. Paragraph 243 of the Complaint purports to quote from federal regulations, the contents of which speak for themselves.

244. Paragraph 244 of the Complaint purports to quote from federal regulations, the contents of which speak for themselves.

245. Paragraph 245 of the Complaint purports to quote from federal regulations, the contents of which speak for themselves.

Response to "K. The Generic Drug Approval Framework"

246. Paragraph 246 of the Complaint reference a federal law, the contents of which speak for themselves.

247. Paragraph 247 of the Complaint purports to state the purpose of a federal law, the contents of which speak for themselves.

248. Paragraph 248 of the Complaint purports to quote from a federal statute, the contents of which speak for themselves.

249. Paragraph 249 of the Complaint purports to summarize federal regulations governing ANDA applications, the contents of which speak for themselves. The allegations in Paragraph 249 of the Complaint are otherwise denied.

Response to "1. ANDA Applications Must Demonstrate Bioequivalence"

250. Paragraph 250 of the Complaint purports to summarize the purpose of ANDA regulations, the contents of which speak for themselves.

251. Paragraph 251 of the Complaint purports to summarize regulations governing ANDA submissions, the contents of which speak for themselves.

252. Paragraph 252 of the Complaint purports to summarize federal statutory provisions governing generic drug manufacturers, the contents of which speak for themselves.

253. Paragraph 253 of the Complaint purports to summarize a federal statutory provision governing generic drug manufacturers, the contents of which speak for themselves.

Response to "2. ANDA Applications Must Provide Information About the Manufacturing Plants and Processes"

254. Paragraph 254 of the Complaint purports to summarize federal regulations governing ANDA applications, the contents of which speak for themselves.

255. Paragraph 255 of the Complaint purports to summarize federal regulations governing ANDA applications, the contents of which speak for themselves.

256. Paragraph 256 of the Complaint purports to summarize federal regulations governing ANDA applications, the contents of which speak for themselves.

Response to "3. ANDA Applications Must Comply with cGMPs"

257. Paragraph 257 of the Complaint purports to summarize federal regulations governing ANDA applications, the contents of which speak for themselves.

258. Paragraph 258 of the Complaint purports to summarize federal regulations governing ANDA applications, the contents of which speak for themselves.

Response to "4. ANDA Approval is Contingent upon Continuing Compliance with ANDA Representations of Sameness"

259. The ZHP Defendants deny the allegations in Paragraph 259 of the Complaint, except state that the referenced statements by the FDA speak for themselves.

260. The ZHP defendants deny the allegations in Paragraph 260 of the Complaint.

261. The ZHP defendants deny the allegations in Paragraph 261 of the Complaint.

262. Paragraph 262 of the Complaint purports to summarize an unidentified FDA statement, the contents of which speak for themselves.

Response to "L. Approval of ANDAs Related to Valsartan"

Response to "1. DIOVAN and EXFORGE Background"

263. In response to the allegations in Paragraph 263 of the Complaint, the ZHP Defendants admit that Valsartan is indicated for the treatment of hypertension, heart failure and post-myocardial infarction. The ZHP Defendants are otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 263 of the Complaint and therefore deny same.

264. In response to the allegations in Paragraph 264 of the Complaint, the ZHP Defendants admit that Valsartan and its combination therapy with hydrochlorothiazide are the generic versions of DIOVAN and DIOVAN HCT, which were marketed by Novartis AG. The ZHP Defendants are otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 264 of the Complaint and therefore deny same.

265. The ZHP Defendants admit the allegations in Paragraph 265 of the Complaint.

266. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 266 of the Complaint and therefore deny same.

267. The ZHP Defendants deny the allegations in Paragraph 267 of the Complaint.

268. Paragraph 268 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response, except that the ZHP Defendants admit that there are generic versions of valsartan.

Response to "2. ANDA Applications for Generic Valsartan"

269. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 269 of the Complaint.

270. Paragraph 270 of the Complaint purports to summarize the provisions of the Hatch-Waxman Act, the contents of which speak for themselves.

271. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 271 of the Complaint and therefore deny same.

272. Paragraph 272 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

273. Paragraph 273 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

274. In response to Paragraph 274 of the Complaint, the ZHP Defendants admit that Prinston d/b/a Solco filed ANDAs for VCDs. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 274 of the Complaint as they relate in part to other, non-answering defendants, and therefore deny same.

275. In response to the allegations in Paragraph 275 of the Complaint, the ZHP Defendants admit that as of the date when Diovan's patent expired, no generic valsartan had been approved in the U.S.

276. The allegations in Paragraph 276 of the Complaint state legal conclusions and do not require a response. To the extent a response is required, the ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 276 of the Complaint and therefore deny same.

277. Paragraph 277 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

278. Paragraph 278 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

279. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 279 of the Complaint and therefore deny same.

280. Paragraph 280 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

281. Paragraph 281 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

Response to "M. Starting as Early as 2007, Defendants Were Actively Violating cGMPs in Their Foreign Manufacturing Facilities"

282. The ZHP Defendants deny the allegations in Paragraph 282 of the Complaint.

283. The ZHP Defendants deny the allegations in Paragraph 283 of the Complaint.

Response to "1. ZHP's Inadequate Manufacturing Processes Results in Contaminated, Adulterated, Misbranded, and/or Unapproved VCDs"

284. Paragraph 284 purports to characterize statements on ZHP's website, the contents of which speak for themselves.

285. ZHP admits that it manufactured API for generic valsartan manufactured by other defendants. The remainder of the allegations in Paragraph 285 of the Complaint state a legal conclusion and do not require a response. In all other respects, the allegations are denied.

286. The ZHP Defendants deny the allegations in Paragraph 286 of the Complaint.

287. The ZHP Defendants deny the allegations in Paragraph 287 of the Complaint, except they admit that the referenced FDA inspection took place and note that the contents of any FDA statements regarding that inspection speak for themselves.

288. The ZHP Defendants deny the allegations in Paragraph 288 of the Complaint, except they admit that the referenced FDA inspection took place and note that the contents of any FDA statements regarding that inspection speak for themselves.

289. The ZHP Defendants deny the allegations in Paragraph 289 of the Complaint, except they admit that the referenced FDA inspection took place and note that the contents of any FDA statements regarding that inspection speak for themselves.

290. The ZHP Defendants deny the allegations in Paragraph 290 of the Complaint.

291. The ZHP Defendants deny the allegations in Paragraph 291 of the Complaint, except that the referenced statements by the FDA speak for themselves.

292. The ZHP Defendants deny the allegations in Paragraph 292 of the Complaint, except that the referenced statements by the FDA speak for themselves.

293. The ZHP Defendants deny the allegations in Paragraph 293 of the Complaint, except they admit that the FDA issued a Warning Letter in 2018, the contents of which speak for themselves.

294. The ZHP Defendants deny the allegations in Paragraph 294 of the Complaint, except they admit that the FDA issued a Warning Letter in 2018, the contents of which speak for themselves.

295. The ZHP Defendants deny the allegations in Paragraph 295 of the Complaint, except they admit that the FDA issued a Warning Letter in 2018, the contents of which speak for themselves.

296. The ZHP Defendants deny the allegations in Paragraph 296 of the Complaint, except they admit that the FDA issued a Warning Letter in 2018, the contents of which speak for themselves.

297. The ZHP Defendants deny the allegations in Paragraph 297 of the Complaint, except they admit that the FDA issued a Warning Letter in 2018, the contents of which speak for themselves.

298. In response to Paragraph 298 of the Complaint, the ZHP Defendants admit that the FDA issued a Warning Letter in September 2018, the contents of which speak for themselves.

299. Paragraph 299 of the Complaint purports to quote from and summarize an FDA press release, the contents of which speak for themselves.

300. Paragraph 300 of the Complaint purports to summarize an FDA Laboratory analysis, the contents of which speak for themselves. The ZHP defendants deny the remainder of the allegations in Paragraph 300 of the Complaint.

Response to "2. Aurobindo's Inadequate Manufacturing Processes Results in Contaminated, Adulterated, Misbranded, and/or Unapproved VCDs"

301. Paragraphs 301-315 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "3. Mylan's Inadequate Manufacturing Processes Results in Contaminated, Adulterated, Misbranded, and/or Unapproved VCDs"

316. Paragraphs 316-346 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "4. Hetero's Inadequate Manufacturing Processes Results in Contaminated, Adulterated, Misbranded, and/or Unapproved VCDs"

347. Paragraph 347-360 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "N. The Contamination of the VCDs"

Response to "1. The Nitrosamine Contaminant NDMA"

361. Paragraph 361 purports to summarize a statement by the Centers for Disease Control and Prevention ("CDC"), the contents of which speak for themselves.

362. Paragraph 362 of the Complaint purports to quote a statement from an Environmental Protection Agency ("EPA") fact sheet, the contents of which speak for themselves.

363. Paragraph 363 of the Complaint references the EPA fact sheet quoted in Paragraph 362 of the Complaint, the contents of which speak for themselves.

364. Paragraph 364 of the Complaint references the EPA fact sheet quoted in Paragraph 362 of the Complaint, the contents of which speak for themselves.

365. Paragraph 365 of the Complaint references the EPA fact sheet quoted in Paragraph 362 of the Complaint, the contents of which speak for themselves. The ZHP Defendants deny any allegation that there is reliable scientific evidence establishing that the trace amounts of NDMA identified in certain VCDs are capable of causing cancer in humans.

366. Paragraph 366 of the Complaint references the EPA fact sheet quoted in Paragraph 362 of the Complaint, the contents of which speak for themselves. The ZHP Defendants admit that there are multiple sources of NDMA exposure in the human population.

367. Paragraph 367 of the Complaint references the EPA fact sheet quoted in Paragraph 362 of the Complaint, the contents of which speak for themselves. The ZHP Defendants deny any allegation that there is reliable scientific evidence

establishing that the trace amounts of NDMA identified in certain VCDs are capable of causing liver damage in humans.

368. Paragraph 368 of the Complaint references a report, the contents of which speak for themselves. To the extent a response is required, the ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 368 of the Complaint and therefore deny same.

369. Paragraph 369 of the Complaint references a statement by the CDC, the contents of which speak for themselves. The ZHP Defendants deny any allegation that there is reliable scientific evidence establishing that the trace amounts of NDMA identified in certain VCDs are capable of causing liver damage in humans.

370. The ZHP Defendants deny the allegations in Paragraph 370 of the Complaint as stated except that the contents of any scientific studies referenced therein speak for themselves. The ZHP Defendants further deny any allegation that there is reliable scientific evidence establishing that the trace amounts of NDMA identified in certain VCDs are capable of causing cancer in humans.

371. Paragraph 371 of the Complaint quotes from an FDA press release, the contents of which speak for themselves.

372. Paragraph 372 of the Complaint quotes from an EPA fact sheet, the contents of which speak for themselves.

373. Paragraph 373 of the Complaint purports to quote or summarize several regulatory documents, the contents of which speak for themselves.

Response to "2. The Nitrosamine Contaminant NDEA"

374. Paragraph 374 of the Complaint references an EPA document, the contents of which speak for themselves.

375. Paragraph 375 of the Complaint references a Canadian regulatory document, the contents of which speak for themselves.

376. The ZHP Defendants deny the allegations in Paragraph 376 of the Complaint.

377. The ZHP Defendants deny the allegations in Paragraph 377 of the Complaint, except to the extent they purport to reference an unidentified EPA statement, the contents of which, if it exists, speak for themselves.

378. Paragraph 378 of the Complaint references an EPA document, the contents of which speak for themselves.

379. Paragraph 379 of the Complaint references at EPA statement, the contents of which speak for themselves. The ZHP Defendants otherwise deny the allegations in Paragraph 379 of the Complaint.

380. Paragraph 380 of the Complaint quotes a New Jersey Department of Health document, the contents of which speak for themselves.

381. Paragraph 381 of the Complaint quotes a New Jersey Department of Health document, the contents of which speak for themselves.

382. Paragraph 382 of the Complaint quotes a New Jersey Department of Health document, the contents of which speak for themselves.

383. Paragraph 383 of the Complaint references an International Agency for Research on Cancer document, the contents of which speak for themselves. Otherwise, the ZHP Defendants deny the allegations in Paragraph 383 of the Complaint.

Response to "3. Formation of NDMA and/or NDEA in Defendants' Contaminated, Adulterated, Misbranded, and/or Unapproved VCDs"

384. Paragraph 384 of the Complaint references an online publication, the contents of which speak for themselves. The ZHP Defendants deny any allegation that there is reliable scientific evidence establishing that the trace amounts of NDMA identified in certain VCDs are capable of causing cancer in humans.

385. Paragraph 385 of the Complaint references an online publication, the contents of which speak for themselves. The ZHP Defendants deny the remainder of the allegations in Paragraph 385 of the Complaint.

386. Paragraph 386 of the Complaint references an online publication, the contents of which speak for themselves. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations

regarding other members of the "pharmaceutical industry" included in Paragraph 386 of the Complaint and therefore deny same. The ZHP Defendants also deny any allegation that they were aware of the possibility of the formation of NDMA in valsartan API prior to June 2018.

Response to "O. Defendants Had Actual and/or Constructive Notice of NDMA and/or NDEA Contamination of their Contaminated, Adulterated, Misbranded, and/or Unapproved VCDs"

387. The ZHP Defendants deny the allegations in Paragraph 387 of the Complaint, except to the extent it quotes a statement by the FDA, the contents of which speak for themselves.

388. The ZHP Defendants deny the allegations in Paragraph 388 of the Complaint.

389. The ZHP Defendants deny the allegations in Paragraph 389 of the Complaint.

390. The ZHP Defendants admit the allegations in the first sentence of Paragraph 390 of the Complaint. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 390 of the Complaint as they relate in part to other, non-answering defendants, and therefore deny same.

391. Paragraph 391 of the Complaint quotes a statement from the European Medicines Agency, the contents of which speak for themselves. In all other respects, the allegations in Paragraph 391 of the Complaint are denied.

392. The ZHP Defendants deny the allegations in Paragraph 392 of the Complaint.

393. The ZHP Defendants deny the allegations in Paragraph 393 of the Complaint.

394. The ZHP Defendants deny the allegations in Paragraph 394 of the Complaint, except to the extent it quotes an FDA regulation, the contents of which speak for themselves.

395. The ZHP Defendants deny the allegations in Paragraph 395 of the Complaint to the extent it applies to them.

396. The ZHP Defendants deny the allegations in Paragraph 396 of the Complaint.

397. The ZHP Defendants deny the allegations in Paragraph 397 of the Complaint.

398. The ZHP Defendants deny the allegations in Paragraph 398 of the Complaint, except to the extent Plaintiffs quote an FDA statement, the contents of which speak for themselves.

399. The ZHP Defendants deny the allegations in Paragraph 399 of the Complaint.

400. The ZHP Defendants deny the allegations in Paragraph 400 of the Complaint.

401. The ZHP Defendants deny the allegations in Paragraph 401 of the Complaint, except that Solco and Huahai US are subsidiaries of ZHP with offices in New Jersey.

402. The ZHP Defendants deny the allegations in Paragraph 402 of the Complaint.

Response to "P. Other Contaminants"

403. The ZHP Defendants deny the allegations in Paragraph 403 of the Complaint.

Response to "Q. FDA Announces Voluntary Recall of Defendants' Contaminated, Adulterated, and/or Misbranded VCDs"

404. The ZHP Defendants deny the allegations in Paragraph 404 of the Complaint, except they admit that there was a voluntary valsartan recall in 2018 and further state that the referenced FDA news release speaks for itself.

405. Paragraph 405 of the Complaint references a news release by the FDA, the contents of which speak for themselves.

406. Paragraph 406 of the Complaint quotes from an FDA document, the contents of which speak for themselves.

407. Paragraph 407 of the Complaint references a statement by the FDA, the contents of which speak for themselves.

408. The ZHP Defendants deny the allegations in Paragraph 408 of the Complaint.

Response to "R. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic VCDs."

409. The ZHP Defendants deny the allegations in Paragraph 409 of the Complaint.

410. The ZHP Defendants deny the allegations in Paragraph 410 of the Complaint.

Response to "1. Warranties Common to all Manufacturer Defendants"

411. The ZHP Defendants admit the allegations in the first two sentences of Paragraph 411 of the Complaint. Further answering, the ZHP Defendants state that the FDA's requirements for inclusion of medications in the "Orange Book" speak for themselves.

412. Paragraph 412 of the Complaint purports to characterize unidentified statements in the FDA's Orange Book, the contents of which, if they exist, speak for themselves.

413. The ZHP Defendants deny the allegations in Paragraph 413 of the Complaint.

414. In response to Paragraph 414 of the Complaint, the ZHP Defendants admit that Prinston d/b/a Solco's VCDs were accompanied by patient information sheets but deny that ZHP, as an API manufacturer, created or distributed patient information sheets for VCDs. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding other defendants that are included in Paragraph 414 of the Complaint and therefore deny same.

415. The ZHP Defendants deny the allegations in Paragraph 415 of the Complaint.

416. The ZHP Defendants deny the allegations in Paragraph 416 of the Complaint.

417. The ZHP Defendants deny the allegations in Paragraph 417 of the Complaint.

418. The ZHP Defendants deny the allegations in Paragraph 418 of the Complaint.

419. The ZHP Defendants deny the allegations in Paragraph 419 of the Complaint.

420. The ZHP Defendants deny that ZHP, as the manufacturer of valsartan API, made any implied warranties with respect to VCDs. The ZHP Defendants otherwise admit the allegations in Paragraph 420 of the Complaint.

421. The ZHP Defendants deny the allegations in Paragraph 421 of the Complaint.

422. The ZHP Defendants deny the allegations in Paragraph 422 of the Complaint.

423. The ZHP Defendants deny the allegations in Paragraph 423 of the Complaint.

424. The ZHP Defendants deny the allegations in Paragraph 424 of the Complaint.

425. Paragraph 425 of the Complaint purports to characterize statements by the FDA, the contents of which speak for themselves. In all other respects, the allegations in this paragraph are denied.

426. The ZHP defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 426 of the Complaint and therefore deny same.

427. The ZHP Defendants deny the allegations in Paragraph 427 of the Complaint.

Response to "2. ZHP Defendants' Warranties"

428. ZHP denies the allegations in Paragraph 428 of the Complaint except to the extent it purports to quote ZHP's website, the contents of which speak for themselves.

429. Huahai US and Prinston deny the allegations in Paragraph 429 of the Complaint as stated.

430. Prinston denies the allegations in Paragraph 430 of the Complaint except to the extent it purports to quote Prinston's website and unidentified marketing materials, the contents of which speak for themselves.

431. Solco denies the allegations in Paragraph 431 of the Complaint except to the extent it purports to quote Solco's website and unidentified marketing materials, the contents of which speak for themselves.

432. In response to Paragraph 432 of the Complaint, Solco states that the referenced portions of its website speak for themselves.

433. In response to Paragraph 433 of the Complaint, Solco states that the referenced portions of its website speak for themselves.

Response to "3. Hetero Defendants' Warranties"

434. Paragraphs 434-438 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "4. Myland Defendants' Warranties"

439. Paragraphs 439-443 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "5. Torrent Defendants' Warranties"

444. Paragraph 444 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

Response to "6. Aurobindo Defendants' Warranties"

445. Paragraphs 445-449 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "7. Teva Defendants' Warranties"

450. Paragraphs 450-458 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "8. Warranties Common to all Retail Pharmacy Defendants"

459. Paragraphs 459-462 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "9. Wholesaler Defendants' Warranties"

463. Paragraph 463 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

Response to "10. Repackager and Relabeler Defendants' Warranties"

464. Paragraphs 464-465 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "S. Wholesaler and Retail Pharmacy Defendants' Obligations to Ensure that the Product they Distribute and Sell

Throughout the Stream of Commerce is Not Suspected to be Adulterated or Misbranded and therefore Illegal to Sell"

466. Paragraphs 466-519 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "1. Defendant McKesson"

520. Paragraphs 520-533 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "2. Cardinal Health"

534. Paragraphs 534-545 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "3. AmerisourceBergen"

546. Paragraphs 546-553 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "4. CVS"

554. Paragraphs 554-563 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "5. Walgreens"

564. Paragraphs 564-574 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "6. Rite-Aid"

575. Paragraphs 575-581 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "7. Walmart"

582. Paragraphs 582-594 of the Complaint are not directed to the ZHP Defendants and therefore do not require a response.

Response to "T. Revelations Continue to Unfold About Other Manufacturing Plants"

595. The ZHP Defendants deny the allegations in Paragraph 595 of the Complaint, except that the referenced announcements by the FDA speak for themselves.

Response to "U. Fraudulent Concealment and Tolling"

596. The ZHP Defendants deny the allegations in Paragraph 596 of the Complaint.

597. The ZHP Defendants deny the allegations in Paragraph 597 of the Complaint.

598. The ZHP Defendants deny the allegations in Paragraph 598 of the Complaint.

599. The ZHP Defendants deny the allegations in Paragraph 599 of the Complaint.

600. The ZHP Defendants deny the allegations in Paragraph 600 of the Complaint, except that the referenced statements on Solco's website, if they exist, speak for themselves.

601. The ZHP Defendants deny the allegations in Paragraph 601 of the Complaint.

602. The ZHP Defendants deny the allegations in Paragraph 602 of the Complaint.

RESPONSE TO "V. CLASS ACTION ALLEGATIONS"

603. The ZHP Defendants admit that Plaintiffs have brought the above-captioned lawsuit as a putative class action.

604. The ZHP Defendants admit that Plaintiffs defined their proposed classes as set forth in Paragraph 604 of the Complaint.

605. The ZHP Defendants deny the allegations in Paragraph 605 of the Complaint.

606. Paragraph 606 of the Complaint and its subparts address consumer claims that are not at issue in the upcoming TPP trial.

607. Paragraph 607 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

608. Paragraph 608 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

609. The ZHP Defendants deny the allegations in Paragraph 609 of the Complaint.

610. The ZHP Defendants deny the allegations in Paragraph 610 of the Complaint.

611. Paragraph 611 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

612. The ZHP Defendants deny the allegations in Paragraph 612 of the Complaint.

613. The ZHP Defendants admit that the numerosity element of Rule 23 is satisfied.

614. The ZHP Defendants deny the allegations in Paragraph 614 of the Complaint and its subparts.

615. The ZHP Defendants deny the allegations in Paragraph 615 of the Complaint.

616. The ZHP Defendants deny the allegations in Paragraph 616 of the Complaint.

617. The ZHP Defendants deny the allegations in Paragraph 617 of the Complaint.

618. The ZHP Defendants deny the allegations in Paragraph 618 of the Complaint.

RESPONSE TO "FIRST CAUSE OF ACTION – BREACH OF EXPRESS WARRANTIES (INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS MEMBERS AGAINST MANUFACTURER DEFENDANTS)"

619. The ZHP Defendants restate and incorporate by reference each of the preceding Paragraphs of this Answer.

620. Paragraph 620 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

621. The ZHP Defendants deny the allegations in Paragraph 621 of the Complaint.

622. The ZHP Defendants deny the allegations in Paragraph 622 of the Complaint.

623. The ZHP Defendants deny the allegations in Paragraph 623 of the Complaint.

624. The ZHP Defendants deny the allegations in Paragraph 624 of the Complaint.

625. Paragraph 625 of the Complaint states a legal conclusion and does not require a response.

626. Paragraph 626 of the Complaint purports to list various state laws, the contents of which speak for themselves.

627. Paragraph 627 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

628. The ZHP Defendants deny the allegations in Paragraph 628 of the Complaint.

629. The ZHP Defendants deny the allegations in Paragraph 629 of the Complaint.

630. The ZHP Defendants deny the allegations in Paragraph 630 of the Complaint.

631. The ZHP Defendants deny the allegations in Paragraph 631 of the Complaint.

632. The ZHP Defendants deny the allegations in Paragraph 632 of the Complaint.

RESPONSE TO "SECOND CAUSE OF ACTION – BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS (INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS MEMBERS AGAINST MANUFACTURER DEFENDANTS)"

633. The ZHP Defendants restate and incorporate by reference each of the preceding Paragraphs of this Answer.

634. Paragraph 634 does not include any factual or legal allegation requiring an admission or denial.

635. Paragraph 635 of the Complaint purports to list various state laws, the contents of which speak for themselves.

636. Paragraph 636 does not include any factual or legal allegation requiring an admission or denial.

637. Paragraph 637 of the Complaint states a legal conclusion and does not require a response.

638. Paragraph 638 of the Complaint states a legal conclusion and does not require a response.

639. Paragraph 639 of the Complaint states a legal conclusion and does not require a response.

640. In response to Paragraph 640 of the Complaint, the ZHP Defendants deny that ZHP, as the manufacturer of API, placed VCDs in sealed packaging or other closed containers and placed them on the market. The ZHP defendants otherwise admit the allegations in Paragraph 640 of the Complaint.

641. The ZHP Defendants deny the allegations in Paragraph 641 of the Complaint.

642. The ZHP Defendants deny the allegations in Paragraph 642 of the Complaint.

643. Paragraph 643 of the Complaint is not addressed to the ZHP Defendants and does not require a response.

644. The ZHP Defendants deny the allegations in Paragraph 644 of the Complaint.

645. The ZHP Defendants deny the allegations in Paragraph 645 of the Complaint.

646. The ZHP Defendants deny the allegations in Paragraph 646 of the Complaint.

647. The ZHP Defendants deny the allegations in Paragraph 647 of the Complaint.

648. The ZHP Defendants deny the allegations in Paragraph 648 of the Complaint.

649. The ZHP Defendants deny the allegations in Paragraph 649 of the Complaint.

650. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 650 of the Complaint regarding Plaintiffs' actions and therefore deny same.

651. The ZHP Defendants deny the allegations in Paragraph 651 of the Complaint.

RESPONSE TO "THIRD CAUSE OF ACTION – BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS (INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS MEMBERS AGAINST WHOLESALER DEFENDANTS)"

652. This cause of action is not alleged against the ZHP Defendants and does not require a response.

RESPONSE TO "FOURTH CAUSE OF ACTION – BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS (INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS ONLY AGAINST PHARMACY DEFENDANTS)"

670. This cause of action is not alleged against the ZHP Defendants and does not require a response.

RESPONSE TO "FIFTH CAUSE OF ACTION – FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION AND CONCEALMENT) (INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS MEMBERS AGAINST MANUFACTURER DEFENDANTS)"

688. The ZHP Defendants restate and incorporate by reference each of the preceding Paragraphs of this Answer.

689. Paragraph 689 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

690. Paragraph 690 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

691. The ZHP Defendants deny the allegations in Paragraph 691 of the Complaint.

692. The ZHP Defendants deny the allegations in Paragraph 692 of the Complaint.

693. The ZHP Defendants deny the allegations in Paragraph 693 of the Complaint.

694. The ZHP Defendants deny the allegations in Paragraph 694 of the Complaint.

695. The ZHP Defendants deny the allegations in Paragraph 695 of the Complaint.

696. The ZHP Defendants deny the allegations in Paragraph 696 of the Complaint.

697. The ZHP Defendants deny the allegations in Paragraph 697 of the Complaint.

698. The ZHP Defendants deny the allegations in Paragraph 698 of the Complaint.

699. The ZHP Defendants deny the allegations in Paragraph 699 of the Complaint.

700. The ZHP Defendants deny the allegations in Paragraph 700 of the Complaint.

701. The ZHP Defendants deny the allegations in Paragraph 701 of the Complaint.

702. The ZHP Defendants deny the allegations in Paragraph 702 of the Complaint.

RESPONSE TO "SIXTH CAUSE OF ACTION – NEGLIGENT MISREPRESENTATION AND OMISSION (INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS MEMBERS AGAINST MANUFACTURER DEFENDANTS)"

703. The ZHP Defendants restate and incorporate by reference each of the preceding Paragraphs of this Answer.

704. Paragraph 704 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

705. Paragraph 705 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

706. The ZHP Defendants deny the allegations in Paragraph 706 of the Complaint.

707. The ZHP Defendants deny the allegations in Paragraph 707 of the Complaint.

708. The ZHP Defendants deny the allegations in Paragraph 708 of the Complaint.

709. Paragraph 709 of the Complaint is not directed to the ZHP Defendants and therefore does not require a response.

710. The ZHP Defendants deny the allegations in Paragraph 710 of the Complaint.

711. The ZHP Defendants deny the allegations in Paragraph 711 of the Complaint.

712. The ZHP Defendants deny the allegations in Paragraph 712 of the Complaint.

713. The ZHP Defendants deny the allegations in Paragraph 713 of the Complaint.

714. The ZHP Defendants deny the allegations in Paragraph 714 of the Complaint.

715. The ZHP Defendants deny the allegations in Paragraph 715 of the Complaint.

716. The ZHP Defendants deny the allegations in Paragraph 716 of the Complaint.

717. The ZHP Defendants deny the allegations in Paragraph 717 of the Complaint.

718. The ZHP Defendants deny the allegations in Paragraph 718 of the Complaint.

719. The ZHP Defendants deny the allegations in Paragraph 719 of the Complaint.

RESPONSE TO "SEVENTH CAUSE OF ACTION – VIOLATION OF STATE CONSUMER PROTECTION LAWS (INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS MEMBERS AGAINST MANUFACTURER DEFENDANTS")

720. The ZHP Defendants restate and incorporate by reference each of the preceding Paragraphs of this Answer.

721. Paragraph 721 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

722. Paragraph 722 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

723. The ZHP Defendants deny the allegations in Paragraph 723 of the Complaint and its subparts.

724. Paragraph 724 of the Complaint states a legal conclusion and does not require a response.

725. The ZHP Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 725 of the Complaint regarding Plaintiffs' and putative class members' purchases of VCDs and therefore deny same.

726. The ZHP Defendants deny the allegations in Paragraph 726 of the Complaint.

727. The ZHP Defendants deny the allegations in Paragraph 727 of the Complaint.

728. The ZHP Defendants deny the allegations in Paragraph 728 of the Complaint.

729. The ZHP Defendants deny the allegations in Paragraph 729 of the Complaint.

730. The ZHP Defendants deny the allegations in Paragraph 730 of the Complaint.

731. The ZHP Defendants deny the allegations in Paragraph 731 of the Complaint.

732. The ZHP Defendants deny the allegations in Paragraph 732 of the Complaint.

733. The ZHP Defendants deny the allegations in Paragraph 733 of the Complaint.

734. The ZHP Defendants deny the allegations in Paragraph 734 of the Complaint.

735. The ZHP Defendants deny the allegations in Paragraph 735 of the Complaint.

736. The ZHP Defendants deny the allegations in Paragraph 736 of the Complaint.

737. The ZHP Defendants deny the allegations in Paragraph 737 of the Complaint.

738. The ZHP Defendants deny the allegations in Paragraph 738 of the Complaint.

739. The ZHP Defendants deny the allegations in Paragraph 739 of the Complaint.

RESPONSE TO "EIGHTH CAUSE OF ACTION – VIOLATION OF STATE CONSUMER PROTECTION LAWS (INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS MEMBERS AGAINST WHOLESALER DEFENDANTS)"

740. This cause of action is not alleged against the ZHP Defendants and does not require a response.

RESPONSE TO "NINTH CAUSE OF ACTION – VIOLATION OF STATE CONSUMER PROTECTION LAWS (INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST RETAIL PHARMACY DEFENDANTS)"

760. This cause of action is not alleged against the ZHP Defendants and does not require a response.

RESPONSE TO "TENTH CAUSE OF ACTION – UNJUST ENRICHMENT (INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)"

780. This cause of action is not at issue in the TPP trial.

RESPONSE TO "ELEVENTH CAUSE OF ACTION – UNJUST ENRICHMENT (INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)"

789. This cause of action is not alleged against the ZHP Defendants and does not require a response.

RESPONSE TO "TWELFTH CAUSE OF ACTION – NEGLIGENCE (INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS MEMBERS AGAINST MANUFACTURER DEFENDANTS)"

798. The ZHP Defendants restate and incorporate by reference each of the preceding Paragraphs of this Answer.

799. Paragraph 799 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

800. Paragraph 800 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

801. Paragraph 801 of the Complaint states a legal conclusion that does not require a response.

802. The ZHP Defendants deny the allegations in Paragraph 802 of the Complaint.

803. The ZHP Defendants deny the allegations in Paragraph 803 of the Complaint.

804. The ZHP Defendants deny the allegations in Paragraph 804 of the Complaint.

805. The ZHP Defendants deny the allegations in Paragraph 805 of the Complaint.

806. The ZHP Defendants deny the allegations in Paragraph 806 of the Complaint.

807. The ZHP Defendants deny the allegations in Paragraph 807 of the Complaint.

808. The ZHP Defendants deny the allegations in Paragraph 808 of the Complaint.

RESPONSE TO "THIRTEENTH CAUSE OF ACTION – NEGLIGENCE PER SE (INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS MEMBERS AGAINST MANUFACTURER DEFENDANTS)"

809. The ZHP Defendants restate and incorporate by reference each of the preceding Paragraphs of this Answer.

810. Paragraph 810 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

811. Paragraph 811 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

812. Paragraph 812 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

813. Paragraph 813 of the Complaint states a legal conclusion that does not require a response.

814. The ZHP Defendants deny the allegations in Paragraph 814 of the Complaint.

815. The ZHP Defendants deny the allegations in Paragraph 815 of the Complaint.

816. The ZHP Defendants deny the allegations in Paragraph 816 of the Complaint.

817. The ZHP Defendants deny the allegations in Paragraph 817 of the Complaint.

818. The ZHP Defendants deny the allegations in Paragraph 818 of the Complaint.

RESPONSE TO "FOURTEENTH CAUSE OF ACTION – STATE-LAW PRODUCT LIABILITY ACT CLAIM UNDER LOUISIANA LAW (INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS, EXCEPT AS TO TPP CLASS MEMBERS

AGAINST PHARMACY DEFENDANTS)"

819. Paragraph 819 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

820. The ZHP Defendants restate and incorporate by reference each of the preceding Paragraphs of this Answer.

821. The ZHP Defendants deny that the Louisiana plaintiffs are entitled to relief under any of the theories listed in Paragraph 821 of the Complaint.

822. The ZHP Defendants deny that the Louisiana plaintiffs are entitled to relief under any legal theory.

823. Paragraph 823 of the Complaint does not include any factual or legal allegation requiring an admission or denial.

AFFIRMATIVE DEFENSES

Without assuming any burden of proof that they would not otherwise bear with respect to the required elements of Plaintiffs' claims, the ZHP Defendants hereby assert the following affirmative defenses to the allegations and claims in the Complaint. All of the following defenses are pleaded in the alternative, and none constitutes an admission that the ZHP Defendants are liable in any way liable to Plaintiffs, that Plaintiffs have been or will be injured or damaged in any way, or that Plaintiffs are entitled to any relief.

The ZHP Defendants further incorporate by reference any defenses applicable to them that are asserted by any other Defendant as if fully set forth herein. The ZHP Defendants reserve the right to assert other defenses as this action proceeds or amend their Answer and hereby give notice that they may further supplement the facts regarding their currently pleaded defenses, based on information that may become available or apparent as this case proceeds to trial.

As a defense to the Complaint and each and every allegation contained therein, the ZHP Defendants assert:

1. **Venue:** Venue is improper with respect to certain Defendants.

2. **Personal Jurisdiction:** This Court does not have personal jurisdiction over ZHP.

3. **Statute of Limitations:** Plaintiffs' and the class members' breach-of-warranty claims are barred by the applicable statutes of limitations. The implied-warranty claims in subclass group d are all governed by a four-year statute of limitations. Because no discovery rule applies to these claims, the causes of action accrued at the time the medications were purchased, barring any claims to the extent they were filed more than four years after that pertinent event. (*See* ECF No. 2261 at G-45 (New York) and G-48 to G-53.) Similarly, the relevant limitations periods for the express warranty classes in subclass d are either six years (Mississippi and Wisconsin) or four years (all other states in the subclass) and the relevant laws

likewise do not recognize any discovery rule. (*See* ECF No. 2261 at F-33 to F-50.) Accordingly, the class members' express warranty claims are barred to the extent they were filed more than four or six years after the medications were prescribed and purchased.

4. **Superseding/Intervening Cause:** To establish proximate cause, Plaintiffs must prove that the ZHP Defendants' alleged misrepresentations, omissions or purported breaches of warranty caused doctors to prescribe, and insurers to cover, the purportedly contaminated medications. However, in prescribing the ZHP defendants' medications, health care professionals relied on a variety of materials and information and had access to many sources of information about those medications, including the medications' FDA-approved labeling, which informed physicians of the risks and benefits of these medications. Many other independent, superseding and unforeseeable causes and/or intervening events similarly broke any causal chain, including individual patients' preferences, patients' decision to fill a prescription and patients' decision whether and how to use the medication. *See, e.g.*, *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S., LLP*, 20 F. Supp. 3d 305, 337 (E.D.N.Y. 2014) (granting defendants summary judgment on state-law consumer-protection claims, reasoning that TPPs' "generalized proof is insufficient to establish that those physicians who would have prescribed a less expensive antibiotic than Ketek (or no antibiotic at all) would not

have prescribed Ketek absent Defendants' deceptive acts and omission."); *In re Vioxx Prods. Liab. Litig.*, MDL 1657, 2010 U.S. Dist. LEXIS 142767, at *23-24 (E.D. La. Mar. 31, 2010) (rejecting at summary judgment theory by Louisiana Attorney General as third-party payor that fewer Vioxx prescriptions would have been written—and thus fewer Medicaid dollars spent—but for Merck's alleged misrepresentations and omissions about Vioxx because"[t]he effect that any alleged misrepresentations had on each" "doctor and each patient" "decision is unique"). In short, any alleged damages in this case were the result of superseding and/or intervening causes over which the ZHP Defendants had no control.

5. **State of the Art:** Plaintiffs' and the class members' claims are barred, in whole or in part, because the products at issue were designed, manufactured, and marketed in accordance with all applicable governmental regulations and the generally recognized state of the art at the time those products were designed, manufactured, labeled and distributed. Liability may not be imposed as to a properly manufactured prescription drug distributed with information regarding the risks of which the manufacturer knew at the time of manufacture, and liability may not be imposed for untold risks not known at the time of such design, manufacture, and sale of the subject prescription drug. The products at issue were not unreasonably dangerous or defective, were suitable for the purpose for which intended, and were distributed with adequate and sufficient warnings. As determined by the FDA, the

risk of not taking VCDs "greatly outweighs the potential risk of exposure to trace amounts of nitrosamines."

6. **Defendants' Good Faith:** Plaintiffs' and the class members' claims are barred, in whole or in part, because all actions taken with regard to Plaintiffs were for lawful business reasons and in good faith. The ZHP Defendants did not know—and could not have reasonably known—of the potential for the manufacturing processes at issue in this litigation to form NDMA and NDEA prior to the FDA's letter in 2018. Indeed, one of Plaintiffs' own experts, Dr. Ramin Najafi, who has a Ph.D. in chemistry and runs a testing laboratory, expressly admitted that he did not know it was possible for the reaction used by ZHP in the TEA with quenching process to result in the formation of NDEA prior to being retained in this litigation. (Dep. of Ramin Najafi, Ph.D. 192:18-193:7, Jan. 18, 2023.)

7. **Regulatory Compliance:** Plaintiffs' claims are barred, in whole or in part, because ZHP's API and Prinston d/b/a Solco's VCDs, at all times relevant hereto, complied with all applicable laws and regulations, as well as all applicable industry and FDA standards, statutes, rules, regulations and guidance at the time they were designed, manufactured, tested, marketed, and labeled. At the time ZHP's API and Prinston d/b/a Solco's VCDs were designed, manufactured, tested, marketed, labeled, and/or distributed, they were approved by the FDA in all respects, including the design formulation requirements, labeling and warnings content,

and/or manufacturing specifications to which they were subjected by the FDA in granting and maintaining Abbreviated New Drug Application approval, as applicable.

8. **Offset:** In the unlikely event that the ZHP Defendants are found liable to Plaintiffs and the class members, they are entitled to a credit, set-off, or offset for any and all sums that Plaintiffs and class members have received, or may hereafter receive, including, but not limited to, by way of any and all settlements arising from Plaintiffs' alleged injuries, claims and causes of action.

9. **Sophisticated User:** Plaintiffs' claims are barred in whole or in part by the sophisticated user defense.

10. **Consent And/Or Ratification:** Plaintiffs' and the class members' claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent they have received and paid for medications manufactured, marketed and sold by the ZHP Defendants after the filing of the Complaint or becoming aware of the events alleged therein.

11. **Punitive Damages:** Plaintiffs' claims for punitive or other exemplary damages are barred in whole or in part by the due process clauses of any applicable state and United States Constitutions, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States

Constitution. Any law, statute or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) unconstitutionally may permit recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not direct, or did not proximately cause harm, if any, to Plaintiffs; (4) unconstitutionally may permit recovery of punitive damages in an amount not reasonable or proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards for appellate review of punitive damages awards; or (7) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *BMW of North America, Inc. v. Gore*, 517 US 559 (1996); *TXO Production Corp. v. Alliance Resources, Inc*., 509 U.S. 443 (1993); *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S.1 (1991); and *State Farm Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

12. **Reservation of Rights:** The ZHP Defendants hereby give notice that they intend to rely upon such other defenses as may become available or appear during the course of proceedings in this case and hereby reserve the right to amend this Answer to assert such defenses. The ZHP Defendants also reserve the right to assert other and related defenses as may become available upon a determination of the law applicable to the action or any part thereof or claim therein. Additionally, the ZHP Defendants hereby give notice that they intend to rely upon and incorporate by reference any affirmative defenses that may be asserted by any codefendant in this litigation.

JURY TRIAL DEMANDED

The ZHP Defendants hereby demand a trial by jury on all issues so triable.

WHEREFORE, the ZHP Defendants request that Plaintiffs' Complaint be dismissed in its entirety with prejudice, that judgment be entered in the ZHP Defendants' favor, and that the Court provide the ZHP Defendants all other such relief as it deems proper.

Dated: March 5, 2024

Respectfully submitted,

By: /s/ *Jessica Davidson*

Jessica Davidson (NY Bar No. 6034748)
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
One Manhattan West
New York, New York 10001
Phone: (212) 735-3222

Fax: (917) 777-3222
jessica.davidson@skadden.com

Nina R. Rose (DC Bar No. 975927)
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
Phone: (202) 371-7000
Fax: (202) 661-0525
nina.rose@skadden.com

Attorneys for Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare U.S., LLC

CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of March 2024, I caused a true and correct copy of the foregoing to be filed with the Court's ECF system and served upon counsel of record.

/s/ Jessica Davidson
Jessica Davidson
Skadden, Arps, Slate, Meagher & Flom LLP